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| APPLICATION NO.             | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------------------|-------------|----------------------|---------------------|------------------|
| 09/880,503                  | 06/13/2001  | Douglas B. Cines     | 53893-5034          | 5341             |
| 28977                       | 7590        | 10/02/2003           | EXAMINER            |                  |
| MORGAN, LEWIS & BOCKIUS LLP |             |                      | LIU, SAMUEL W       |                  |
| 1701 MARKET STREET          |             |                      | ART UNIT            |                  |
| PHILADELPHIA, PA 19103-2921 |             |                      | PAPER NUMBER        |                  |

1653

DATE MAILED: 10/02/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

## Application No.

09/880,503

## Applicant(s)

CINES ET AL.

## Examiner

Samuel W Liu

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-55 is/are pending in the application.
- 4a) Of the above claim(s) none is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-55 are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s) \_\_\_\_.
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_ 6) ☐ Other: \_\_\_\_\_

### DETAILED ACTION

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-2, 6-9, 11-12, 14-18, 22, 24-26, 28 and 54-55, drawn to a composition comprising the urokinase-type plasminogen activator (uPA) kringle domain, classified in class 514, subclass 12, and class 530, subclass 300 and 350.
- II. Claims 3-4, 10, 13, 19-21, 23, 27-28 and 54-55, drawn to a composition comprising the growth factor domain of uPA, classified in class 514, subclass 12, and class 530, subclass 300 and 350.
- III. Claim 29, drawn to a composition comprising the polynucleotide, classified class 536, subclass 23.1, class 437, subclass 94, and class 514, subclass 44.
- IV. Claims 30-44 and 46-50, drawn to a method of treating a disease or condition associated with abnormal muscular contractility or endothelial angiogenic disorder comprising administering to a subject composition comprising the uPA *Kringle domain*, classified class 514, subclass 12, and class 424, subclasses 94.1 and 94.6.
- V. Claim 45, drawn to a method of identifying an agonist or antagonist compound (*in vitro*) for the uPA kringle domain, or/and, the uPA growth factor domain, or/and a binding protein thereof, (ligand-protein interaction), classified class 435, subclass 7.1, class 514, subclass 12, and class 424, subclasses 94.1 and 94.6.
- VI. Claims 51-52, drawn to a method of identifying the binding of a test protein to a polypeptide of the uPA kringle domain (protein-protein interaction), or/and, the uPA growth factor domain, or/and the connecting peptide and identifying a functional unit comprising the polypeptide thereof, classified in class 435, subclasses 7.1 and 18 class 514, subclass 12, and class 424, subclasses 94.1 and 94.6.
- VII. Claim 53, drawn to a method of treating a vascular disease comprising administering to a subject the composition comprising the polypeptide(s) derived

from the uPA or/and an antagonist molecule of the polypeptide thereof, classified in class 514, subclass 12, class 435, subclass 7.1, and class 424, subclasses 94.1 and 94.6.

The inventions are distinct, each from the other because of the following reasons:

Inventions I, II and III are patentably distinct from one another because the compositions of the Inventions comprise the polypeptides which are distinct in structure as well as lengths of the polypeptide sequences. The biopolymers of each invention would be expected to exhibit different physical and chemical properties, and are capable of separate manufacture or use.

Inventions IV-VII are directed to different and/or distinct methods. Although there are no provisions under the section for "Relationship of Invention" in MPEP 806.05 for inventive groups that are directed to different methods, restriction is deemed to be proper between the methods of Invention IV – VII since they constitute patentably distinct inventions comprising methodologies, starting material, objectives, technical considerations, ingredients, endpoint or/and disease state and treatment outcome. Therefore, each method is patentably distinct.

Invention I is related to Inventions IV, V, VI and VII as product and processes of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the polypeptide(s) of the composition can be used to raise antibody(ies) against the polypeptide(s) thereof, for example.

Invention II is related to Inventions IV, V, VI and VII as product and processes of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the polypeptide(s) of the composition can be used to raise antibody(ies) against the polypeptide(s) thereof, for example.

Invention III is unrelated to Inventions IV, V, VI and VII. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01).

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In the instant case the mechanism of using polynucleotide (e.g., hybridization) is distinct from the mode of action of the polypeptide binding to an agonist or antagonist molecule, for example.

*Additional Election Under 35 USC 121*

Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed 37 C.F.R. 1.143). In the response, applicant is to indicate (1) the elected group and indicate (2) the further election as required below.

When Group I is elected, applicant is required under 35 US 121 to elect/identify:

(i) one muscle tissue from claim 7 because the smooth muscle, striated muscle and cardiac muscle are different tissue from one another;

(ii) one compound from claims 8 and 18 since the recited compounds are both structurally and functionally distinct/different from one another; and

(iii) peptide component(s) of the composition from claims 2, 28 and 54 for examination of the elected invention on the merits, since each polypeptide is distinct/different in structure and function or/and since a combination of the polypeptides thereof determines biological and pharmaceutical properties of the claimed compositions. Each composition comprising the polypeptide(s) is patentably distinct.

When Group II is elected, applicant is required under 35 US 121 to elect/identify:

(i) one polypeptide or polypeptide(s) from claim 28 which comprises the composition since each polypeptide SEQ ID NO represents the structurally distinct/different molecule;

(ii) one mutant polypeptide from claims 23 since each mutated polypeptide is distinct in structure and biological activity; and

(iii) peptide component(s) of the composition from claims 4 and 54 for examination of the elected invention on the merits, since each polypeptide is distinct/different in structure and function or/and since a combination of the polypeptides thereof determines biological and pharmaceutical properties of the claimed compositions. Each composition comprising the polypeptide(s) is patentably distinct.

When Group III is elected, applicant is required under 35 US 121 to elect/identify (from claim 29) polypeptide(s) of which the claimed composition comprises since the polypeptides are

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distinct or/and distinct from one other and since the peptide component of the composition must be identified for examination of the elected invention on the merits.

When Group IV is elected, applicant is required under 35 US 121 to elect/identify:

- (i) one polypeptide from claim 31 because the SEQ ID NOs of the polypeptides are distinct in structure and length thereof;
- (ii) one amino acid sequence from claim 35 because the SEQ ID NOs of the polypeptides show distinct structure and length thereof;
- (iii) one disease state from claim 39 since each disease state has distinct/different pathological mechanism, treatment step(s), administering route, and outcome of treatment;
- (iv) one amino acid sequence of the uPA kringle from claim 40 because the sequences are distinct in structure;
- (v) one agonist or antagonist of the composition from claim 46 wherein the peptide component(s) of the composition must be identified for examination of the elected invention on the merits, since antagonist has inverse pharmacological effect, as opposed to agonist, on outcome of the claimed method of treating a disease state; and
- (vi) one disease state from claim 49 since each disease state has distinct/different pathological mechanism, treatment step(s), administering route, and outcome of treatment.

Further, when Group IV or V or VI or VII is elected, applicant is required under 35 US 121 to elect/identify the peptide component(s) of the composition for examination of the elected invention on the merits, since each polypeptide is distinct/different in structure and function or/and since a combination of the polypeptides thereof determines biological and pharmaceutical properties of the claimed compositions. Each composition-determined method is thus patentably distinct.

In the above, the response to the election requirement should also identify the claims readable thereon as directed to the elected invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

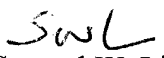
Application/Control Number: 09/880,503

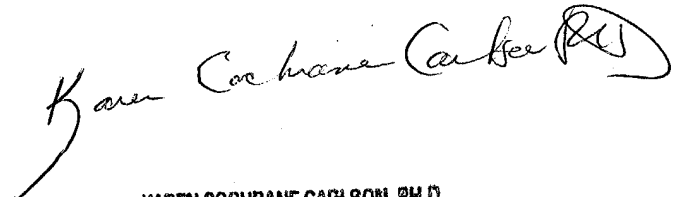
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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Samuel Wei Liu, Ph.D. whose telephone number is 703-306-3483. The examiner can normally be reached Monday-Friday 9:00 -5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Christopher Low can be reached on (703) 308-2923. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 for regular communication and (703) 305-3014 for the after final communication. Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 1600 receptionist whose telephone number is (703) 308-0196.

  
Samuel W. Liu, Ph.D.  
September 23, 2003

  
KAREN COCHRANE CARLSON, PH.D.  
PRIMARY EXAMINER